

**657—20.16 (124,126,155A) Compounding for hospital use.** Compounded preparations distributed or dispensed to a hospital or hospital pharmacy pursuant to this rule shall be administered to an individual patient in the hospital.

**20.16(1)** *By an FDA-registered outsourcing facility.* Only an FDA-registered outsourcing facility properly licensed in Iowa may distribute human compounded preparations to a hospital or hospital pharmacy in the absence of a patient-specific prescription. The compounded preparation shall be labeled in compliance with subrule 20.19(3).

**20.16(2)** *By a pharmacy that is not an FDA-registered outsourcing facility.* Human compounded preparations that are not compounded at an FDA-registered outsourcing facility may be dispensed to a hospital or hospital pharmacy by an Iowa-licensed pharmacy pursuant to a prescriber's authorization for administration to a specific patient. The compounded preparation shall be labeled in compliance with subrule 20.19(2).

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